



Standard Operating Procedure: #8
IRB Review of Human Subjects Research – Full Board
Revision Date: October 2020

Overview:

Human subjects research that is not Exempt or eligible for Expedited Review must be reviewed at a convened meeting of the IRB. The IRB may review research through the Full Board procedures if:

- The research is greater than minimal risk;
- An expedited review refers application to a Full Board review; OR
- The research is deemed as other non-exempt research

Procedures

1. IRB Meetings are convened on a regular schedule that is published by January 1st of each year. IRB Members may participate in person or via teleconference.
2. Meeting materials will be distributed at least three (3) days prior to the meeting and will include:
 - a. Agenda
 - b. Minutes from the previous meeting
 - c. Expedited Review Summary
 - d. Applications for Full Board review/approval including all pertinent documentation (i.e. informed consent documents, collaborator's documentation, etc.). The Principal Investigator (PI) submitting the application is invited to attend the IRB meeting to answer questions, clarify specific points, or for discussion.

3. The IRB Chair will call the meeting to order.

A quorum must be maintained to take action / votes at a convened meeting. A majority (half plus one) of the IRB members, at least one nonscientific member and one non-affiliated member must be present throughout the meeting to maintain a quorum. Should members with conflicts of interest leave the meeting for deliberation and voting, it could negate quorum.

A convened meeting that has not met quorum may continue with reviewing studies to provide the PI feedback to improve the submission, but cannot conduct any official business, *i.e.*, vote for approval.

If a representative of a special group of subjects is deemed necessary, the representative must be present as a voting member, *i.e.*, a prisoner representative for a study involving prisoners.

4. The IRB Chair will ask for any conflicts of interest (COI) or modifications to agenda items. When an application has been introduced and clarification has been provided to the IRB, the PI and/or any IRB members with a COI will be asked to leave the meeting while the IRB deliberates and makes a decision.
5. The IRB members in attendance will discuss the application and motion to vote (a simple majority of the members present is needed for the vote). The motion will be to vote on one of the four actions below:
 - Approve the application without conditions

- Approve the application with conditions
 - This is communicated to the PI through the IRB Program Manager.
 - Upon acceptance of conditions, the IRB Chair will approve the application.
 - Table / Defer decision
 - This is communicated to the PI through the IRB Program Manager.
 - The PI can resubmit the application with major revisions requested and/or additional information for rereview at the next regularly scheduled meeting.
 - Disapprove the application
 - IRB members present determine that the risk of the procedures outweigh any benefit to be gained or the application does not meet the federal criteria for the IRB approval – even with major revisions to the application the issues prevent approval and will not be resolved.
 - The IRB Program Manager communicates the decision to the PI with a letter that describes the reasons for disapproval.
 - The PI may respond in writing and the response will be reviewed at the next regularly scheduled meeting (which the PI will be invited to attend).
6. For an approved application:
- An approval letter will be generated and signed by the IRB Chair.
 - The approved protocol package will include:
 - Signed approval letter
 - Submitted application
 - Pertinent documentation related to the application (i.e. consent forms, study materials, etc.)
 - The IRB Program Manager will send an email to notify PI that the study has been approved. The email will have the approved protocol package attached.
 - The approved protocol will be entered into the DOE IRB database.
 - The protocol and all application documentation will follow *SOP #18: Retention of IRB Records*
6. All applications discussed will be captured in the meeting minutes with sufficient details to show the actions taken by the IRB members present, the vote on the actions and a summary of the discussion of any controverted issues and their resolution and include all items as identified in *SOP #18: Retention of IRB Records*.



Document Review History

Revision Number	Date	Author	Summary of Changes
01	September 2017	Ann-Marie Dake	Complete Revision
02	November 2018	Dawn Whalen	Document control process added
03	November 2019	IRB Office	Complete Revision
04	October 2020	Ann-Marie Dake	Revisions and updates